510K Summary

July 13, 2011

K111177

SEP 12 2011

Trade Name : JUELLCure Hard

Common Name: Hard impression material

Company Contact:

John Roderick, Operations Manager
Juell Dental
2401 N. Commerce
Ardmore, OK 73401
(580) 798-4414

Classification Name – Resin, denture, relining, repairing, rebasing

CFR Section: 872.3760

FDA Device Class: Class II

FDA Product Code : EBI

Classification Panel : Dental

Device Description: JuellCure hard is a cold-curing, hard relining material for permanently relining dentures.

Indications for Use:

JUELL Hard Cure is intended for use as a permanent hard relining for total and partial dentures

- hard permanent total or partial relining for restoring partial- and complete dentures
- lengthening denture margins

Performance Testing:

Testing including adhesion to denture material, thermocycling, flexural strength, color stability, heat of polymerization, and translucency were conducted. The values for these performance characteristics was found to be very similar to the predicate device.

Predicate Device: Ufi Gel hard C, K030916, VOCO GmbH, Germany

K111177

Substantial Equivalence:

	Juell Hard Cure	Ufi Gel Hard C K030916
Indications for Use	JUELL Hard Cure is intended for use as a permanent hard relining for total and partial dentures • hard permanent total or partial relining for restoring partial- and complete dentures • lengthening denture margins	Ufi Gel Hard C is intended for use as a permanent hard relining for total and partial dentures • hard permanent total or partial relining for restoring partial- and complete dentures • lengthening denture margins
Setting Time	135-180 seconds	135-180 seconds
Appearance	Paste is a colorless, homogenous liquid and the catalyst is a white homogenous paste.	Paste is a colorless, homogenous liquid and the catalyst is a white homogenous paste.
Composition of Catalyst	Matrix 40-60% Filler 30-40% Catalyst 2-4% Modifier 6-7% Stabilizer <0.1%	Matrix 40-60% Filler 30-40% Catalyst 2-4% Modifier 6-7% Stabilizer <0.1%
Composition of Paste	Monomer : HEDMA, UDMA, Bis-GMA 30-50% Filler 40-60% Colorant <0.1% Modifier 5-6% Stabilizer <0.1%	Monomer : HEDMA, UDMA, Bis-GMA 30-50% Filler 40-60% Colorant <0.1% Modifier 5-6% Stabilizer <0.1%
Flexural Strength	78 Mpa	78 Mpa
Translucency of 2mm specimens	44%	44%

Juell Hard Cure is substantially equivalent to VOCO Ufi Gel Hard C in regards to composition, indications for use and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Juell Dental
C/O Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
2401 N Commerce
Ardmore, Oklahoma 73401

SEP 12 2011

Re: K111177
Trade/Device Name: JuellCure Hard
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: August 30, 2011
Received: September 1, 2011

Dear Ms. Blackwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K111177

Device Name: _____JuellCure Hard_____

Indications for Use:

JuellCure Hard is intended for use as a permanent hard relining for total and partial dentures

- Hard permanent total or partial relining for restoring partial and complete dentures
- Lengthening denture margins

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111177